



Division of Dockets Management (HFA-305)

Food & Drug Administration

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Attention: <http://www.fda.gov/dockets/ecomments>

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Fonterra (USA) Inc Submission on Department of Health and Human Services US Food and Drug Administration " Public Health Security and Bioterrorism Preparedness and Response Act of 2002"

Docket No 02N-0278

Prior Notice of Imported Food Section 307

30 April 2004

Fonterra (USA) Inc (formerly NZMP (USA) Inc d/b/a/ Fonterra (USA), 635 North 12th street, Suite 101, Lemoyne, Pennsylvania 17043 USA, is a wholly-owned subsidiary of Fonterra Co-operative Group Ltd., Auckland, New Zealand. Fonterra Co-operative Group is one of the largest companies in New Zealand, accounting for 20% of the New Zealand GDP and 7% of New Zealand' s Total Exports by Value, and is one of the top ten largest global dairy traders across open borders in the world (July 2003 figures) Fonterra Co-operative Group Ltds supply chain stretches from New Zealand shareholders' farms to customers and consumers in 140 countries. The Co-operative collects over 13 Billion litres of milk per year and manufactures and markets over 1.8 million tonnes of product annually.

Fonterra (USA) imports a wide range of these New Zealand origin dairy products, subject to regulations administered by the Food and Drug Administration, accounting for approximately 45% of U.S. dairy product imports (2002 data), accounting for over \$500M of imported value per year, supplying some of the largest and most well-known brands in America. We are therefore heavily impacted by the FDA Bioterrorism Act' s Interim Final Rules on Facility Registration and Prior Notice submission.

Fonterra (USA) supports the efforts of the FDA in its implementation of the Bioterrorism Act and its intent to safeguard the food supply in the United States. We share in the FDAs interest in this goal and applaud the efforts made in this regard, including the to-date modifications that have been implemented as a result of comments such as these from industry. We herewith respectfully submit further comments on the Interim Final Rules to continue to partner with the FDA in this matter.

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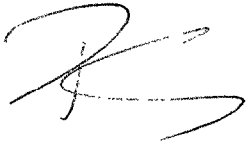
Prior Notice

- There should be a *de minimus* provision for samples for known shippers/importers that is cross referenced by
 - Shipper Facility Registration
 - Manufacturer Facility Registration
 - Importer Facility Registration
 - Low Value
 - Low Weight
- There are inadequate provisions for re-submission of a rejected PN
 - Please consider having a resubmission automatically cancel the original.
- Prior Notice submissions should be coordinated with advanced Manifest rules to eliminate duplication of data submissions.
- Please clarify your process for food held/refused then later deemed to be admissible;
- Please consider doing the OASIS review concurrently with the FDA BTA review to eliminate re-work and burden on both the importing community and the FDA;
 - Please resolve the conflict with CBPs live entry requirements.
- Enforcement actions should be based on levels of culpability (negligent, grossly negligent, fraudulent), number of infractions, seriousness of infractions
 - Please consider this when writing the penalty provisions
- What are the penalties for inadvertent errors in the PN submission (clerical, etc.)?
- The inadequacy of a PN submission will be communicated primarily to the CARRIER.
 - We request that the FDA amend this process such that the submitter and/or the importer are also notified.
- There are no adequate provisions for tracking amendments; an import can be made and then amended without amendment to the PN
 - Please address this risk area.
- Changes to PN should be for MATERIAL changes ONLY. Materiality TBD;
- There is no facility registration requirement for transshippers, however CF7512s (T&E, I.T.s) require a PN to be filed. This cannot be accomplished without the corresponding facility registration number. Moreover, in the case of T&Es and I.T.s, there is no designated submitter. We respectfully request that T&E and I.T. transactions be exempt from PN requirement.

Other

- 4 hours to production of records is only feasible for current year records. Archived records may not be retrievable in this time frame.
 - Please consider when implementing record keeping requirements.
- Since the Interim Final Rules are not fully tested, we request that the rules be maintained as interim final for a longer period of time with phased implementation.

Fonterra (USA) sincerely thanks FDA for its efforts to improve upon the interim final rules on facility registration to balance security requirements with business realities. We look forward to further modifications to make this process the most secure and least burdensome possible.



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